

Consultant year-end index

VOLUME 24, JANUARY-DECEMBER 1984

INDEX TO MAJOR SUBJECTS

- Abdomen**, pain, identifying gastrointestinal causes. Al-Jurf AS. 84 Dec 67.
- Acidosis**, diabetic, which route best for insulin delivery? (Brf Consult). Malone JL. 84 Feb 126.
- Adolescence**, detecting psychopathology in outpatient setting. Mitchell JR, Rothenberg MB. 84 March 267.
- Aged**, assessing mental incompetence. Ratzan RM. 84 Dec 88.
- evaluating hematologic abnormalities. Baserga SJ, Benz EJ Jr. 84 March 309.
- urinary tract dysfunction in the elderly. Badlani G, Smith AD. 84 June 181.
- Aging**, and nutritional needs. Russell RM, Whinston-Perry R. 84 Aug 67.
- and memory dysfunction. Pomara N, Block R, Gershon S. 84 Nov 136.
- Airway obstruction**, upper, in children. Wagener JS. 84 Sept 115.
- Allergens**, choosing diagnostic procedures Marquardt DL, Wasserman SL. 84 Jan 151.
- Anorexia**, managing complications after cure (Brf Consult). Breen JL, Raisz LG, Quigley MM. 84 Sept 107.
- Anti-inflammatory agents**, nonsteroidal, selection criteria. Huskisson EC. 84 March 41.
- Antibiotics**, selecting for anaerobic infections. Derk FW, Sanders CV, Marier RL. 84 Jan 206.

(Abbreviations:
Brf Consult=Brief Consultation;
Puzz Case=Puzzling Case)

- Antibodies**, detecting disorders. Stites DP. 84 Jan 284.
- Arrhythmia**, ECG patterns (Part 2). Schwartz AB, Scheinman MM. 84 May 238.
- managing arrhythmias. Garson A Jr. 84 Nov 99.
- patterns on ECG (Part 1). Schwartz AB, Scheinman MM. 84 April 275.
- post-bypass, management. Slosky DA, Martinsen KS, Doucette M. 84 Oct 115.
- Arterial occlusive diseases**, noninvasive diagnostic techniques to use in the office. Spittell JA. 84 July 214.
- Arteriosclerosis**, food and arterial plaques (Brf Consult). Connor W, Wolinsky H. 84 May 106.
- Arthritis**, infectious, treatment. Sack KE. 84 Oct 101.
- rheumatoid, and aspirin, physicians' questions (10). Eisenberg GM, Arnold WJ. 84 June 31.
- rheumatoid, intractable. See **Clinical Case No. 121**. 84 Sept 158.
- Arthroplasty**, picking candidates for total hip replacement. Wolfgang GL. 84 March 209.
- Aspirin**, and rheumatoid arthritis, physicians' questions (10). Eisenberg GM, Arnold WJ. 84 June 31.
- Asthma**, don't assume an allergic cause. Wassersug JD. 84 July 97.
- immunotherapy for allergic bronchial. Metzger WJ, Richerson HB. 84 Jan 240.
- Audiology**, pediatric, screening for hearing impairment. Stool SE. 84 March 131.
- Bladder**, neurogenic, therapeutic outlines. Leslie S. 84 Jan 131.

- Body weight**, and the athlete. Smith NJ. 84 Feb 247.
- evaluating loss. Botoman VA, Black, HR. 84 Jan 258.
- Brief Consultations**
- Add prazosin to prevent hyperlipidemia? Nash DT. 84 Dec 107.
- After anorexia, followup. Breen JL, Raisz LG, Quigley MM. 84 Sept 107.
- Antiepileptic: research, dosages, safety. Livingston S. 84 April 123.
- Chelation therapy a hoax? Barrett S. 84 Feb 82.
- Chiropractors and a thermography scam? Patterson MM, Honig S. 84 March 81.
- Cytoprotective prostaglandins. Bynum TE. 84 Jan 115.
- Diets and 'thyroid myth.' Lachance P, Chernev R. 84 Aug 177.
- Duration of warfarin therapy. Naide M, Naide D, Lerner RG, Baron HC. 84 Oct 267.
- 'Electric' paralysis during sleep. Raskind R, Smith RJ. 84 March 145.
- Evaluating tetanus toxoid reaction. Bryan CS. 84 July 212.
- Eye changes and continuous insulin. Danowski TS. 84 June 111.
- Food and arterial plaques. Connor W, Wolinsky H. 84 May 106.
- In danger of renal failure. Black HR, Knochel JP. 84 March 263.
- Insulin delivery. Malone JL. 84 Feb 126.
- Mysterious swelling in one leg. Black HR, Sholl JG. 84 Aug 104.
- Questionable treatment for back pain. Ferguson AB Jr, Weiss TE. 84 Feb 167.

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- Abdomen**, pain, identifying gastrointestinal causes. Al-Jurf AS. 84 Dec 67.
- Acidosis**, diabetic, which route best for insulin delivery? (Brf Consult). Malone JL. 84 Feb 126.
- Adolescence**, detecting psychopathology in outpatient setting. Mitchell JR, Rothenberg MB. 84 March 267.
- Aged**, assessing mental incompetence. Ratzan RM. 84 Dec 88. evaluating hematologic abnormalities. Baserga SJ, Benz EJ Jr. 84 March 309.
- urinary tract dysfunction in the elderly. Badlani G, Smith AD. 84 June 181.
- Aging**, and nutritional needs. Russell RM, Whinston-Perry R. 84 Aug 67.
- and memory dysfunction. Pomara N, Block R, Gershon S. 84 Nov 136.
- Airway obstruction**, upper, in children. Wagener JS. 84 Sept 115.
- Allergens**, choosing diagnostic procedures Marquardt DL, Wasserman SL. 84 Jan 151.
- Anorexia**, managing complications after cure (Brf Consult). Breen JL, Raisz LG, Quigley MM. 84 Sept 107.
- Anti-inflammatory agents**, nonsteroidal, selection criteria. Huskisson EC. 84 March 41.
- Antibiotics**, selecting for anaerobic infections. Derk FW, Sanders CV, Marier RL. 84 Jan 206.

(Abbreviations:
Brf Consult=Brief Consultation;
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- Antibodies**, detecting disorders. Stites DP. 84 Jan 284.
- Arrhythmia**, ECG patterns (Part 2). Schwartz AB, Scheinman MM. 84 May 238.
- managing arrhythmias. Garson A Jr. 84 Nov 99.
- patterns on ECG (Part 1). Schwartz AB, Scheinman MM. 84 April 275.
- post-bypass, management. Slosky DA, Martinsen KS, Doucette M. 84 Oct 115.
- Arterial occlusive diseases**, noninvasive diagnostic techniques to use in the office. Spittell JA. 84 July 214.
- Arteriosclerosis**, food and arterial plaques (Brf Consult). Connor W, Wolinsky H. 84 May 106.
- Arthritis**, infectious, treatment. Sack KE. 84 Oct 101.
- rheumatoid, and aspirin, physicians' questions (10). Eisenberg GM, Arnold WJ. 84 June 31.
- rheumatoid, intractable. See **Clinical Case No. 121**. 84 Sept 158.
- Arthroplasty**, picking candidates for total hip replacement. Wolfgang GL. 84 March 209.
- Aspirin**, and rheumatoid arthritis, physicians' questions (10). Eisenberg GM, Arnold WJ. 84 June 31.
- Asthma**, don't assume an allergic cause. Wassersug JD. 84 July 97.
- immunotherapy for allergic bronchial. Metzger WJ, Richerson HB. 84 Jan 240.
- Audiology**, pediatric, screening for hearing impairment. Stool SE. 84 March 131.
- Bladder**, neurogenic, therapeutic outlines. Leslie S. 84 Jan 131.

- Body weight**, and the athlete. Smith NJ. 84 Feb 247.
- evaluating loss. Botoman VA, Black, HR. 84 Jan 258.
- Brief Consultations**
- Add prazosin to prevent hyperlipidemia? Nash DT. 84 Dec 107.
- After anorexia, followup. Breen JL, Raisz LG, Quigley MM. 84 Sept 107.
- Antiepileptic: research, dosages, safety. Livingston S. 84 April 123.
- Chelation therapy a hoax? Barrett S. 84 Feb 82.
- Chiropractors and a thermography scam? Patterson MM, Honig S. 84 March 81.
- Cytoprotective prostaglandins. Bynum TE. 84 Jan 115.
- Diets and 'thyroid myth.' Lachance P, Chernev R. 84 Aug 177.
- Duration of warfarin therapy. Naide M, Naide D, Lerner RG, Baron HC. 84 Oct 267.
- 'Electric' paralysis during sleep. Raskind R, Smith RJ. 84 March 145.
- Evaluating tetanus toxoid reaction. Bryan CS. 84 July 212.
- Eye changes and continuous insulin. Danowski TS. 84 June 111.
- Food and arterial plaques. Connor W, Wolinsky H. 84 May 106.
- In danger of renal failure. Black HR, Knochel JP. 84 March 263.
- Insulin delivery. Malone JL. 84 Feb 126.
- Mysterious swelling in one leg. Black HR, Sholl JG. 84 Aug 104.
- Questionable treatment for back pain. Ferguson AB Jr, Weiss TE. 84 Feb 167.

- RBBB**—What does it signify? Russell RO Jr. 84 March 295.
- Suspicious salmonella appearance.** McHenry MC, Adler S. 84 Jan 99.
- Timing mitral valve replacement.** Child JS. 84 Sept 127.
- Updated emphysema treatment.** Catz EG, Martin RJ. 84 Oct 179.
- Brucellosis**, diagnosis and treatment. See **Clinical Case No. 118**. 84 June 198.
- Burns**, guide to referring problem cases. Fisher JC. 84 April 76.
- Caffeine**, untoward effects. See **Clinical Case No. 119**. 84 July 194.
- Calcium channel blockers**, pharmacology and clinical uses. Shapiro W. 84 Dec 150.
- Carcinoid tumor** (Puzz Case). Faillace RT, Biddle TL. 84 March 239.
- Cerebral palsy**, early diagnosis. Bennett FC. 84 June 151.
- Cerebrovascular disorders**, why stroke patients behave as they do. Ruskin AP. 84 Feb 177.
- Chelating agents**, therapy a hoax (Brf Consult). Barrett S. 84 Feb 82.
- Child**, chronic headache. Souji ES. 84 Aug 78.
- making school physicals more productive. Driscoll CE. 84 Sept 143.
- managing arrhythmias. Garson A Jr. 84 Nov 99.
- managing upper airway obstruction. Wagener JS. 84 Sept 115.
- opharyngeal injuries. Maisel RH. 84 Jan 186.
- pulmonary valve stenosis. See **Clinical Case No. 120**. 84 Aug 134.
- respiratory and intestinal surgical emergencies in neonates. Howell C. 84 March 149.
- screening for hearing impairment. Stool SE. 84 March 131.
- sleep apnea. Schidlow DV, Bye MR. 84 May 77.
- Circumcision**, neonatal, using local anesthetic Williamson PS. 84 Feb 67.
- Clinical Cases**
- No. 113. 84 Jan 306. The case of the senile executive (normal-pressure hydrocephalus). Amin N.
 - No. 114. 84 Feb 292. Right upper quadrant pain—assume gallstones are the cause? (spinal cord tumor). Raskind R.
 - No. 115. 84 March 282. The case of the college student with something to hide (genital herpes). Dirckx JH.
 - No. 116. 84 April 230. What do these cardiac symptoms mean in a patient with a prosthetic valve? (valve failure). Winniford MD, Firth BG.
 - No. 117. 84 May 204. What are the implications of the lump in her neck? (thyroid neoplasm). Lueg MC.
 - No. 118. 84 June 198. A businessman with fever of unknown origin (brucellosis). Sharma OP.
 - No. 119. 84 July 194. 'Aspirin doesn't help my headaches anymore' (caffeineism). Greenburg JL.
 - No. 120. 84 Aug 134. A 5-year-old with systolic ejection click and murmur (pulmonary valve stenosis). Allen HD.
 - No. 121. 84 Sept 158. What can be done about her intractable rheumatoid arthritis? Searles RP.
 - No. 122. 84 Oct 256. What is causing her left jaw to swell? (Sjögren's syndrome). Deaton JG.
 - No. 123. 84 Nov 158. A 46-year-old woman with persistent vomiting (hypercalcemia). Amin NM.
 - No. 124. 84 Dec 108. Diabetes, organic brain disease, and bedsores—why the sepsis? (spinal cord tumor). Rosenberg R, Ramsby GR.
 - Colitis**, pseudomembranous (Puzz Case). Gray JE. 84 July 121.
 - Coma**, protocol for emergency care. Nesemann ME. 84 Nov 192.
 - Computers**, analysis of ECG. Caceres CA. 84 June 237.
 - Counseling**, teenagers and sexual activity. Smith JA. 84 July 155.
 - Crutches**, instructing their proper use. Cozen LN. 84 Jan 268.
 - Cushing's syndrome**, evaluation. Adlin EV. 84 March 228.
 - Cytological techniques**, gynecologic. Colon VF, Schumann GB. 84 Aug 161.
 - Delivery**, at home, negotiating with parents. Anstett RE, Illige M. 84 July 186.
 - Depression**, choosing appropriate medication (part 2). Camara A, Silverman JJ. 84 Feb 233.
 - who can be helped by medication (part 1). Silverman JJ, Camara A. 84 Jan 37.
 - Diabetes mellitus**, newest approaches for a successful pregnancy. Hollingsworth DR. 84 Aug 29.
 - type II, management. DeFronzo RA. 84 Feb 35.
 - Diabetic nephropathy**, managing complications. Berger B, Vincenti FG. 84 Jan 81.
 - Diagnosis**, when diseases convert to seemingly unrelated disorders. Lichstein J. 84 Oct 299.
 - Diarrhea**, travelers', precautions, prophylaxis, treatment. Ericsson CD. 84 April 195.
 - Diet**, and 'thyroid myth' (Brf Consult). Lachance P, Cherner R. 84 Aug 177.
 - Digitalis**, current controversy in perspective. Ryan TJ. 84 Nov 221.
 - Drugs**, clinical uses of calcium channel blockers. Shapiro W. 84 Dec 150.
 - interactions of sulfonylureas with other compounds. Feldman JM. 84 July 37.
 - measuring plasma concentrations. Pierce CH. 84 May 174.
 - oral hypoglycemics, new and old. Beaser RS. 84 Oct 82.
 - Drug therapy**, cardioprotective effects of antihypertensives. Brest AN. 84 June 111.
 - scrutinizing antihypertensive agents. Cutler RE. 84 March 321.
 - selecting from among NSAIDs. Huskisson EC. 84 March 41.
- Editorial opinion**
- Shahady, Edward J.: Communication between consultants and primary care physicians, 84 Dec 178.
 - Ulrich BS: An informed patient may be a better (calmer) patient, 84 May 252.
 - Why not share your tips with our readers? 84 Nov 232.
- Electrocardiography**, computerized analysis. Caceres CA. 84 June 237.
- Emphysema**, updated treatment (Brf Consult). Catz EG, Martin RJ. 84 Oct 179.
- Endocarditis**, infective, prompt recognition. Mead RH, Harrison DC. 84 April 109.
- Endocrine diseases**, effects of aging on normal and abnormal function. Leebaw WF, Morley JE. 84 July 165.
- Epilepsy**, distinguishing between types of seizures. Livingston S. 84 Oct 237.
- therapy (Brf Consult). Livingston S. 84 April 123.
- Epistaxis**, managing anterior and posterior bleeding sites. Dickens JH, Jacobs JR. 84 July 140.
- Esophageal diseases**, relieving heartburn, dysphagia, chest pain. Castell DO. 84 April 259.
- Exophthalmos**, secondary to Graves' disease. Lueg MC. 84 Feb 193.
- Eye**, changes with continuous insulin administration (Brf Consult). Danowski TS. 84 June 111.
- improved surgery for age-related disorders Kaufman JH. 84 Jan 63.
- Fibromyalgia**, recognizing a common pain syndrome. Goldman AL. 84 July 55.
- Foot**, pain, management strategies. Morvant R, Baxter DE. 84 Aug 146.
- Fractures**, in children. Bucholz RW. 84 Feb 214.
- Gastroenteritis**, acute infectious, identifying viruses and microbes Marzouk JB, Sieber L. 84 July 67.
- Geriatric psychiatry**, helping families cope with problems. Barton R. 84 Sept 67.
- Geriatrics**, evaluating the 'confused' patient. Selbst RA. 84 April 209.
- how functional changes affect clinical decisions. Coodley EL. 84 Oct 39.
- impact of aging on illness. Minaker KL. 84 Feb 328.
- Gout**, complicated by medications (Puzz Case). Healey LA. 84 April 159.
- Gynecology**, improving your cytologic techniques. Colon VF, Schumann GB. 84 Aug 161.
- office biopsy assessment of vulvovaginal neoplasms. Llorens AS. 84 June 129.
- well-woman checkup. Curtis P. 84 Jan 231.

ERYC® (erythromycin capsules, USP)

Before prescribing, please see full prescribing information. A Brief Summary follows.

INDICATIONS AND USAGE: ERYC is indicated in children and adults for the treatment of the following conditions: Upper respiratory tract infections of mild to moderate degree caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci), *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae* (when used concomitantly with adequate doses of sulfonamides, since not all strains of *H. influenzae* are susceptible at the erythromycin concentrations ordinarily achieved). (See appropriate sulfonamide labeling for prescribing information.)

Lower respiratory tract infections of mild to moderate severity caused by *Streptococcus pyogenes* (group A beta hemolytic streptococci); *Streptococcus pneumoniae* (*Diplococcus pneumoniae*).

Respiratory tract infections due to *Mycoplasma pneumoniae* (Eaton's agent).

Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Diphtheria—As an adjunct to antibiotic infections due to *Corynebacterium diphtheriae*, to prevent establishment of carriers and to eradicate the organism in carriers.

Erysipelas—In the treatment of infections due to *Corynebacterium minutissimum*.

Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycin only). Extraenteric amebiasis requires treatment with other agents.

Infections due to *Listeria monocytogenes*.

Skin and soft tissue infections of mild to moderate severity caused by *Streptococcus pyogenes* and *Staphylococcus aureus* (resistant staphylococci may emerge during treatment).

Primary syphilis caused by *Treponema pallidum*. Erythromycin (oral forms only) is an alternate choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid should be examined before treatment and as part of the follow-up after therapy. The use of erythromycin for the treatment of *in utero* syphilis is not recommended (See CLINICAL PHARMACOLOGY in full prescribing information).

Erythromycin are indicated for treatment of the following infections caused by *Chlamydia trachomatis*: conjunctivitis of the newborn, pneumonia of infancy, urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.

Legionnaires' disease caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' disease.

Treatment with erythromycin should be monitored by bacteriological studies and by clinical response (See CLINICAL PHARMACOLOGY—Microbiology in full prescribing information).

Injectable benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long-term prophylaxis of rheumatic fever. When oral medication is preferred for treatment of the above conditions, penicillin G, V, or erythromycin are alternate drugs of choice.

Although no controlled clinical efficacy trials have been conducted, erythromycin has been suggested by the American Heart Association and the American Dental Association for use in a regimen for prophylaxis against bacterial endocarditis in patients allergic to penicillin who have congenital and/or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract. (Erythromycin is not suitable prior to genitourinary surgery where the organisms likely to lead to bacteremia are gram-negative bacilli or the enterococcal group of streptococci.)

NOTE: When selecting antibiotics for the prevention of bacterial endocarditis the physician or dentist should read the full joint 1977 statement of the American Heart Association and the American Dental Association.

CONTRAINDICATION: ERYC is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNING: There have been a few reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving erythromycin succinate, base, and stearate products.

PRECAUTIONS: Caution should be exercised when erythromycin is administered to patients with impaired hepatic function (See CLINICAL PHARMACOLOGY in full prescribing information and WARNING.)

Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Erythromycin interferes with the fluorimetric determination of urinary catecholamines.

Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted.

When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

Pregnancy Category B: Reproduction studies have been performed in rats, mice and rabbits using erythromycin and its various salts and esters, at doses which were several times multiples of the usual human dose. No evidence of impaired fertility or harm to the fetus that appeared related to erythromycin was reported in these studies. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: The effect of ERYC on labor and delivery is unknown.

Nursing Mothers: Erythromycin is excreted in milk (see CLINICAL PHARMACOLOGY in full prescribing information).

Pediatric Use: See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION.

ADVERSE REACTIONS: The most frequent side effects of oral erythromycin preparations are gastrointestinal and dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatic dysfunction and/or abnormal liver function test results may occur (see WARNING).

Mild allergic reactions such as rashes with or without pruritis, urticaria, bullous fixed eruptions, and eczema have been reported with erythromycin. Serious allergic reactions, including anaphylaxis, have been reported.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

DOSAGE AND ADMINISTRATION: Administration of a dose of ERYC in the presence of food lowers the blood levels of systemically available erythromycin. Although the blood levels obtained upon administration of enteric-coated erythromycin products in the presence of food are still above minimum inhibitory concentrations (MICs) of most organisms for which erythromycin is indicated, optimum blood levels are obtained on a fasting stomach (administration at least 1/2 hour and preferably two hours before or after a meal).

Adults: The usual dose is 250 mg every 6 hours taken; one hour before meals. If twice-a-day dosage is desired, the recommended dose is 500 mg every 12 hours. Dosage may be increased up to 4 grams per day, according to the severity of infection. Twice-a-day dosing is not recommended when doses larger than 1 gram daily are administered.

Children: Age, weight, and severity of the infection are important factors in determining the proper dosage. The usual dosage is 30 to 50 mg/kg/day in divided doses. For the treatment of more severe infections, this dose may be doubled.

Streptococcal infections: A therapeutic dosage of oral erythromycin should be administered for at least 10 days. For continuous prophylaxis against recurrences of streptococcal infections in persons with a history of rheumatic heart disease, the dose is 250 mg twice a day.

For the prevention of bacterial endocarditis in penicillin-allergic patients with valvular heart disease who are to undergo dental procedures or surgical procedures of the upper respiratory tract, the adult dose is 1.0 grams orally (20 mg/kg for children) one and one-half to 2 hours prior to the procedure and then 500 mg (10 mg/kg for children) orally every 6 hours for 8 doses. (See INDICATIONS AND USAGE.)

Primary syphilis: 30-40 grams given in divided doses over a period of 10-15 days.

Intestinal amebiasis: 250 mg four times daily for 10 to 14 days for adults; 30 to 50 mg/kg/day in divided doses for 10 to 14 days for children.

Legionnaires' Disease: Although optimal doses have not been established, doses utilized in reported clinical data were those recommended above (1 to 4 grams daily in divided doses).

Urogenital infections during pregnancy due to Chlamydia trachomatis: Although the optimal dose and duration of therapy have not been established, the suggested treatment is erythromycin 500 mg, by mouth, 4 times a day on an empty stomach for at least 7 days. For women who cannot tolerate this regimen, a decreased dose of 250 mg, by mouth, 4 times a day should be used for at least 14 days.

For adults with uncomplicated urethral, endocervical, or rectal infections caused by *Chlamydia trachomatis* in whom tetracyclines are contraindicated or not tolerated: 50 mg, by mouth, 4 times a day for at least 7 days.

Pertussis: Although optimum dosage and duration of therapy have not been established, doses of erythromycin utilized in reported clinical studies were 40-50 mg/kg/day given in divided doses for 5 to 14 days. 0696G081

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PD-10-JA-2159-P-112-841

YEAR-END INDEX

Hamartomatosis, diagnosis (Puzz Case). Martin RJ. 84 Dec 97.

Hands, painful, diagnosis by physical examination only. Weiss TE. 84 Dec 51.

Head, pain, diagnosis. Renner GJ. 84 Oct 185.

Headache, chronic, in children. Souji ES. 84 Aug 78.

Heart, acute failure, medical intervention. Weil MH, Rackow EC. 84 Oct 227.

Current imaging techniques. Newell JD, Raynaud A, Capp MP. 84 May 91.

examination of pulses, rhythms, and rates. DeLeon AC. 84 March 111. timing mitral valve replacement (Brf Consult). Child JS. 84 Sept 127.

Heart diseases, pulmonary valve stenosis in 5-year-old child. See Clinical Case No. 120. 84 Aug 134.

Heart enlargement, diagnostic tests (part 2). Roth R, Abrams J. 84 Feb 107.

office detection of cardiomegaly (part 1). Roth R, Abrams J. 84 Jan 102.

Heart valve prosthesis, failure. See Clinical Case No. 116. 84 April 230.

Hematology, evaluation abnormalities in the elderly. Baserga SJ, Benz EJ Jr. 84 March 309.

Hemothorax, complicated by infection (Puzz Case). Albin RJ. 84 Feb 207.

Herpesvirus, viral, non-A, non-B.

Kleinman MS. 84 May 143. unique aspects during childhood Balistreri WF. 84 April 131.

Herpes genitalis. See Clinical Case No. 115. 84 March 282.

Hip, arthroplasty, picking candidates. Wolfgang GL. 84 March 209.

Hodgkin's disease, new imaging techniques. Hagemeister FB, Fuller LM. 84 Feb 128.

Hydrocephalus, normal-pressure. See Clinical Case No. 113. 84 Jan 306.

Hypocalcemia, secondary to malignancy. Reiss E. 84 Sept 193. See Clinical Case No. 123. 84 Nov 158.

Hyperlipidemia, is prazosin preventative? (Brf Consult). Nash DT. 84 Dec 107.

Hypertension, complicated by hypervolemia. Carr AA. 84 Aug 189.

Hypertension, criteria for diagnosis and initiating therapy. Forsyth RA. 84 Oct 306.

mild, treatment without drugs.

Ziegler MG. 84 Jan 320.

therapy, cardioprotective effects. Brest AN. 84 June 92.

therapy, scrutinizing accepted agents. Cutler RE. 84 March 321.

therapy, simplified regimen for better compliance. Black HR. 84 Feb 333.

Hypoglycemic agents, oral, new drugs and old. Beaser RS. 84 Oct 82.

Impotence, tracing its multifactorial causes. Cohen SN. 84 Aug 121.

Infant, failure to thrive. Hopwood NJ. 84 June 45.

YEAR-END INDEX

- Infection**, anaerobic, choosing antibiotics. Derk FW, Sanders CV, Marier RL. 84 Jan 206.
- postsplenectomy, assessing risk. Gold E. 84 Jan 301.
- update on syphilis. Kelly AP. 84 March 173.
- Influenza vaccine**, recommendations for 1984-85. Douglas RG Jr. 84 Oct 33.
- Insulin**, continuous administration, effects of. Brest AN. 84 June 111.
- Jaundice**, obviating fruitless diagnostic tests. Allison JG. 84 Jan 45.
- Kidney**, management of transplant recipients. Braun WE. 84 Oct 135.
- Kidney calculi**, preventing recurrence. Blath RA. 84 Nov 54.
- Kidney failure**, acute, in danger of (Brf Consult). Black HR, Knochel JP. 84 March 263.
- Kyphosis**, counteracting deformities in children. Micheli LJ, Wolin P. 84 Oct 280.
- Labor**, preterm, who is at risk and how they can be helped. Harris JL. 84 March 256.
- Leg**, mysterious swelling (Brf Consult). Black HR, Sholl JG. 84 Aug 104.
- Legionnaire's disease**, effective therapy. Amin NM. 84 Aug 91.
- Leukocytosis**, gauging its significance. Newland JR. 84 May 221.
- Liver cirrhosis**, biliary, diagnosis and treatment. Carey WD. 84 March 89.
- Liver neoplasms**, optimizing diagnostic aids. Lightdale CJ. 84 Feb 271.
- Lymphoma**, new imaging techniques. Hagemeyer FB, Fuller LM. 84 Feb 128.
- Malabsorption syndromes**, specific tests for small-bowel function. Stella GJ, Dobbins JW. 84 June 113.
- Malignant hyperthermia**, treatment and prevention. Humphrey MJ, Blanck TJ. 84 June 61.
- Mammography**, current recommendations. Egan RI. 84 April 166.
- Memory**, dysfunction in aging. Pomara N, Block R, Gershon S. 84 Nov 136.
- Mental incompetence**, assessing the elderly. Ratzan RM. 84 Dec 88.
- Myocardial infarction**, emergency measures. Cooke DH. 84 Sept 206.
- Myocarditis**, viral, diagnosis. Matsumori A, Abelmann WH. 84 July 127.
- Neoplasms**, and stress. Rosch PJ. 84 Nov 73.
- approach to Class II vaginal smears. Luff RD. 84 Nov 177.
- associated emergencies. Stapczynski JS. 84 Oct 207.
- brain (Puzz Case). Bicknell JM. 84 Nov 206.
- followup after successful treatment. Mortimer J. 84 July 202.
- lowering risk through diet. Newell GR Jr. 84 Jan 116.
- lung, and superior vena cava syndrome (Puzz Case). Lending RE. 84 Feb 321.
- melanoma diagnosis and treatment. Redman JC. 84 Nov 201.
- mouth and throat, earlier diagnosis. Stanley RB Jr. 84 April 81.
- skin, recognition and treatment. Grekin RC, Swanson NA. 84 June 69.
- spinal cord. See **Clinical Case No. 114**. Raskind R. 84 Feb 292.
- spinal cord. See **Clinical Case No. 124**. 84 Dec 108.
- thyroid. See **Clinical Case No. 117**. Lueg MC. 84 May 204.
- vulvovaginal, assessment by office biopsy. Llorens AS. 84 June 129.
- Nutrition**, assessing needs of the elderly. Russell RM, Whinston-Perry R. 84 Aug 67.
- lowering risk of cancer. Newell GR Jr. 84 Jan 116.
- Nutrition disorders**, failure to thrive. Hopwood NJ. 84 June 45.
- Oropharynx**, dealing with injuries in children. Maisel RH. 84 Jan 186.
- Osteoarthritis**, medical management. Jacobs RP. 84 Nov 29.
- Osteoporosis**, management and prevention. Skillman TG. 84 Feb 153.
- Otitis external**, managing dermatologic and otic problems. Hughes MF. 84 May 113.
- Oxygen inhalation therapy**, for hypoxic patients at home. Wade M, Make B. 84 March 57.
- Pain**, back, questionable treatment (Brf Consult). Ferguson AB Jr, Weiss TE. 84 Feb 167.
- clinics, choosing the right one. Murphy TM. 84 July 107.
- foot, management strategies. Morvant R, Baxter DE. 84 Aug 146.
- hands, diagnosis by physical examination only. Weiss TE. 84 Dec 51.
- head, diagnosis. Renner GJ. 84 Oct 185.
- upper abdominal, identifying gastrointestinal causes. Al-Jurf AS. 84 Dec 67.
- Patients**, difficult to deal with. Shahady EJ. 84 April 33.
- Peptic ulcer**, new drugs and current therapy. Rawls DE, Dyck WP. 84 Feb 85.
- Photoclinic**
- 84 Jan 279. Glaucoma, allergic eczematous contact dermatitis, seborrheic keratosis, asymmetric crying face, sarcoidosis
 - 84 Feb 263. Waardenburg's syndrome, acute mastoiditis, necrobiosis lipoidica diabetorum (NLD), purpura, Kaposi's sarcoma, acne.
 - 84 March 247. Toxic epidermal necrolysis (TEN), acne, neonatorum, lentigo maligna melanoma, red lunula, Sturge-Weber syndrome, scleroderma and polymyositis.
 - 84 April 223. Candidal paronychia, porphyria cutanea tarda (PCT), partial albinism, discoid lupus erythematosus, accessory nipple, Collodion baby.
 - 84 May 169. Addison's disease, Schönlein-Henoch purpura,
- morphea, necrotizing streptococcal fasciitis, nephrotic syndrome, rhus dermatitis.
- 84 June 145. Congenital hairy mole, jaundice, jogger's heel, morphaform basal cell carcinoma, paronychia, Darier's sign.
- 84 July 181. Lentigo maligna, amelanotic melanomas, metallic mercury injection, melanoma, Duane's syndrome, acute dacryocystitis, acanthosis nigricans.
- 84 Aug 115. Pyogenic granuloma, hemangioma, fixed drug eruption, acromegaly thyroglossal duct cyst, anetoderma.
- 84 Sept 135. Mycosis fungoidea, Bell's palsy, miliary tuberculosis, Still's disease, salicylate sensitivity.
- 84 Oct 251. Lichen planus hypertrophicus, borderline lepromatous leprosy, eczema herpeticum, hereditary hemorrhagic telangiectasia, caterpillar dermatitis, blue nevus.
- 84 Nov 131. Telangiectasia, spider hemangioma, cavernous hemangioma, Madelung's deformity, scleroderma, lichen sclerosus et atrophicus, angiokeratomas, trichofolliculoma. 84 Dec 95.
- Physical examination**, school, making it more productive. Driscoll CE. 84 Sept 143.
- Pituitary function tests**, simple ways to evaluate complex conditions. Cohen KL. 84 Dec 41.
- Pneumonia**, aspiration, treatment. Mathews J. 84 Dec 25.
- Polycthemia**, interpreting an elevated hematocrit. Wheby MS. 84 Dec 124.
- Practical Pointers** (See also **Tips**)
A wine bottle, acid reflux, and thou. 84 June 177.
- Calm the child with tongue blade. 84 April 130.
- Changing oral endotracheal tubes. 84 April 130.
- Check vitamin K content of anticoagulation supplements. 84 March 106.
- 'Clean' rectal specimen for VD. 84 April 130.
- Cleaning a head wound. 84 July 228.
- Confusion in elderly—organic v hypothermic. 84 Aug 200.
- Counting pills by five. 84 July 228.
- Cremation preparation. 84 Jan 166.
- Determining liver span with stethoscope. 84 Feb 338.
- Easing funduscopic examination in children. 84 Oct 130.
- Easing patient anxiety before proctoscopy. 84 Feb 338.
- Easy access to blood samples. 84 Sept 204.
- Easy catheterization with lidocaine jelly. 84 July 228.
- Easy marsupialization of a Bartholin's cyst. 84 March 106.
- Endotracheal route for drugs. 84 Oct 130.
- Escape-proof restraint. 84 Aug 171.

YEAR-END INDEX

- Facilitating communication with patients who can't speak. 84 March 255.
- Facilitating patient case information. 84 Aug 171.
- False hematuria in urine testing. 84 Feb 125.
- Getting rid of rings. 84 Jan 319.
- Gloved finger fits rectal medication. 84 Nov 27.
- Handy examining room bench. 84 Sept 204.
- Immobilizing a mobile vein. 84 Jan 319.
- Impressive puncture site. 84 Jan 239.
- Instant hot compresses. 84 Aug 200.
- Instant wheelchair. 84 Jan 166.
- 'Lashrub' instead of eyedrops. 84 July 228.
- Measure acetaminophen levels in narcotics overdoes. 84 March 255.
- Minimizing phone interruptions. 84 Oct 130.
- Morning hour phone-in. 84 Oct 130.
- Ointment aid for venipuncture. 84 Oct 130.
- Precision applicator for wart treatment. 84 July 228.
- Prevent recurrent calluses. 84 April 208.
- Preventing aspiration. 84 Jan 319.
- Preventing staph contamination of urine culture. 84 May 48.
- Relieving nail hematomas. 84 May 48.
- Removing impacted pearl from ear. 84 May 48.
- Safeguarding stool testing results. 84 April 208.
- Scalpel better than scissors. 84 Jan 166.
- Smoking, drinking, and phrasing a question. 84 Jan 166.
- Spindle and stack to store tips. 84 June 177.
- Straining reveals a hernia. 84 Feb 338.
- Subtract frustration from pill division. 84 Jan 239.
- Suppressing a pacemaker. 84 Aug 200.
- Syringe-culture technique. 84 March 106.
- System for patient followup. 84 April 208.
- 'Tail-tell' time, medication instructions. 84 June 177.
- Taking a stand on nitrates. 84 Oct 130.
- The damages of broad-spectrum, empiric therapy. 84 Jan 319.
- Tracheal intubation in unconscious patient. 84 Feb 125.
- Tracking neoplasm dimensions. 84 April 130.
- Try a second platelet count before major workup. 84 Nov 27.
- Tuberculin skin test on children. 84 Feb 125.
- Uncovering alcohol abuse. 84 Feb 125.
- Urine testing with methylene blue. 84 Feb 125.
- Wart removal. 84 Nov 27.
- Wound closure strips that stay put. 84 April 130.
- Wrapping up a stool specimen 84 Jan 239.
- Pregnancy**, ensuring its success in a diabetic woman. Hollingsworth DR. 84 Aug 29.
- preterm labor, who is at risk and how they can be helped. Harris JL. 84 March 256.
- Preoperative care**, which test for 'healthy' patients. Goldman L. 84 Jan 331.
- Psychopathology**, adolescent, identifying problems in an outpatient setting. Mitchell JR, Rothenberg MB. 84 March 267.
- Puzzling Cases**
- A cured cold, but with onset of diarrhea (pseudomembranous colitis). Gray JE. 84 July 121.
 - A pain in the neck. Wachtel TJ. 84 Jan 253.
 - Brain tumor and hemiparesis. Bicknell JM. 84 Nov 206.
 - Hamartomatosis. Martin RJ. 84 Dec 97.
 - Hiccups and hyponatremia. Albin RJ. 84 Feb 207.
 - Low back pain: In search of the mysterious cause (spontaneous thrombosis). Lending RE, Buchsbaum HW. 84 June 224.
 - Respiratory sleep disorder. Martin RJ. 84 Sept 113.
 - Spinal cord compression. Whitehouse FW. 84 Oct 199.
 - Suspicious trio: diarrhea, edema, dyspnea (carcinoïd tumor). Faillace RT, Biddle TL. 84 March 239.
 - Was heart disease causing the cyanosis? Lending RE. 84 Feb 321.
 - What was causing the joint pain? (gout). Healey LA. 84 April 159.
- Pyoderma**, differentiating infectious processes. Collins WE, Rosen T. 84 Sept 181.
- Radiation**, ionizing, hazards of medical uses. Fleming MF, Archer VE. 84 Jan 167.
- Radiography**, abdominal, evaluating gas patterns. Doris PE, Birnbaum G. 84 Sept 29.
- Respiratory therapy**, comprehensive rehabilitation. Anholm JD, Hodgkin JE. 84 Feb 73.
- Respiratory tract diseases**, brucellosis. See Clinical Case No. 118. 84 June 198.
- Retinitis pigmentosa**, differentiation from other retinopathies. Heckenlively JR, Ellis DS. 84 May 51.
- Scoliosis**, counteracting deformities in children. Micheli LJ, Wolin P. 84 Oct 280.
- Sex**, counseling teenagers. Smith JA. 84 July 155.
- Sex disorders**, guiding patients to help. Alexander B. 84 June 217.
- Shoulder**, rotator cuff disease diagnosis. Montgomery JB, Jones RE. 84 April 242.
- Sigmoidoscopy**, why you should use the flexible scope. Hocutt JE Jr, Eisenstat TE. 84 May 39.
- Sjögren's syndrome**, See Clinical Case No. 122. 84 Oct 256.
- Skin**, preserving hydration. Dotz WI, Berman B. 84 Aug 46.
- Skin diseases**, pictorial guide to neoplasms. Grekin RC, Swanson NA. 84 June 69.
- Skin manifestations**, of malignancy. Dotz W, Berman B. 84 Oct 268.
- Skin neoplasms**, differentiating benign from malignant. Ragaz A. 84 May 128.
- Sleep**, episodes of paralysis (Brf Consult). Raskind R, Smith RJ. 84 March 145.
- Sleep apnea syndromes**, cause of CHF, hypertension, erythrocytosis (Puzz Case). Martin RJ. 84 Sept 113.
- in children. Schidlow DV, Bye MR. 84 May 77.
- Smoking**, and health. Terry LL. 84 Feb 307.
- Spermatic cord torsion**, how to handle the emergency. Allen TD. 84 March 301.
- Spinal cord compression**, cause of crippling (Puzz Case). Whitehouse FW. 84 Oct 199.
- Splenectomy**, assessing risk of infection. Gold E. 84 Jan 301.
- Sports medicine**, hip and thigh injuries. Friermood TG. 84 May 157.
- safe weight control for athletes. Smith NJ. 84 Feb 247.
- Stress**, and cancer. Rosch PJ. 84 Nov 73.
- Stress disorders**, post-traumatic, helping veterans. Casper E. 84 May 191.
- Sulfonylurea compounds**, interactions with other drugs. Feldman JM. 84 July 37.
- Syphilis**, diagnosis and treatment update. Kelly AP. 84 March 173.
- Testis**, treating spermatic cord torsion. Allen TD. 84 March 301.
- Tetanus toxoid**, reaction (Brf Consult). Bryan CS. 84 July 212.
- Thermography**, advertising by chiropractors a scam? (Brf Consult). Patterson MM, Honig S. 84 March 81.
- Thrombosis**, spontaneous in distal aorta (Puzz Case). Lending RE, Buchsbaum HW. 84 June 224.
- Thyroid neoplasms**, See Clinical Case No. 117. Lueg MC. 84 May 204.
- Tinnitus**, differential diagnosis. Liebman EP. 84 April 47.
- Tips** (See also **Practical Pointers**)
- Abscess dressing. 84 July 112.
 - Amniotic fluid test. 84 Nov 144.
 - Culture vacuum. 84 March 95.
 - Disulfiram and some OTCs don't mix. 84 July 172.
 - Don't overlook this cause of neck pain. 84 Jan 143.
 - Hemorrhoids or a slipped disk? 84 April 116.
 - Jelly without a crust. 84 March 167.
 - Lubricant a washout. 84 July 188.
 - Misleading old-age problems. 84 March 326.
 - Music to tap by. 84 June 96.
 - Padding prevents pressure pain. 84 Feb 159.

Patient pictures. 84 Oct 217.
Puppet palpation. 84 March 136.
Stickers—aid and comfort to kids. 84 Jan 39.
Treats for young patients. 84 June 56.
Venous access via thumb blowing. 84 April 99.
Warming up to cold stethoscope. 84 May 149.
Warm fluid for cold patient. 84 Sept 215.

Tuberculosis, update on drug therapy. Simon HB. 84 April 63.
Urinary tract, dysfunction in the elderly. Badlani G, Smith AD. 84 June 181.
Vaginal smears, newer approach to Class II. Luff RD. 84 Nov 177.
Vaginitis, recurrent. Herbert WNP. 84 Sept 46.
Warfarin, duration of therapy (Brf Consult). Naide M, Naide D, Lerner RG, Baron HC. 84 Oct 267.

When the doctor orders...
Allergy testing (direct skin testing). 84 June 103.
Caloric test. 84 Sept 133.
Computerized tomography. 84 May 127.
Dexamethasone suppression test. 84 July 193.
Intravenous pyelography (IVP). 84 Dec 87.
Lumbar puncture. 84 Nov 217.
Mediastinoscopy. 84 Aug 185.
Radioisotope scanning. 84 Oct 232.

INDEX TO AUTHORS

Abelmann, Walter H recognizing viral myocarditis. 84 July 127.
Abrams, Jonathan evaluation of cardiomegaly. 84 Jan 102; tests for cardiomegaly (part 2). 84 Feb 107.
Adler, Sheldon suspicious salmonella appearance (Brf Consult). 84 Jan 99.
Adlin, E Victor Cushing's syndrome. 84 March 228.
Al-Jurf, Adel S gastrointestinal causes of upper abdominal pain. 84 Dec 67.
Albin, Robert J infected hemothorax (Puzz Case). 84 Feb 207.
Alexander, Beth sexual problems. 84 June 217.
Allen, Hugh D pulmonary valve stenosis (Clinical Case No. 120). 84 Aug 134.
Allen, Terry D testicular torsion. 84 March 301.
Allison, John G jaundice diagnosis and treatment. 84 Jan 45.
Amin, Navin hypercalcemia (Clinical Case No. 123). 84 Nov 158; Legit nnaire's disease. 84 Aug 91; normal-pressure hydrocephalus (Clinical Case No. 113). 84 Jan 306.
Anholm, James D pulmonary rehab (itation). 84 Feb 73.
Anstett, Richard E negotiating with patients for home birth. 84 July 186.
Archer, Victor E hazards of ionizing radiation. 84 Jan 167.
Arnold, William J rheumatoid arthritis and aspirin (physicians' questions). 84 June 31.
Badlani, Gopal urinary tract dysfunction in the elderly. 84 June 181.
Balistreri, William F viral hepatitis during childhood. 84 April 131.
Baron, Howard C duration of warfarin therapy (Brf Consult). 84 Oct 267.
Barrett, Stephen chelation therapy a hoax? (Brf Consult). 84 Feb 82.

Barton, Russell psychiatric problems in the elderly. 84 Sept 67.
Baserga, Susan J hematologic abnormalities in the elderly. 84 March 309.
Baxter, Donald E management strategies for foot pain. 84 Aug 146.
Beaser, Richard S oral hypoglycemics. 84 Oct 82.
Bennett, Forrest C early diagnosis of cerebral palsy. 84 June 151.
Benz, Edward J Jr hematologic abnormalities in the elderly. 84 March 309.
Berger, Bruce diabetic nephropathy. 84 Jan 81.
Berman, Brian skin signs of internal malignancy. 84 Oct 268; ways to preserve skin hydration. 84 Aug 46.
Bicknell, JM brain tumor (Puzz Case). 84 Nov 206.
Biddle, Theodore L carcinoid tumor (Puzz Case). 84 March 239.
Birnbaum, Gary evaluating gas patterns on abdominal x-ray films. evaluating gas patterns on abdominal x-ray films. 84 Sept 29.
Black, Henry R evaluating weight loss. 84 Jan 258; hypertension therapy and compliance. 84 Feb 333; mysterious swelling in one leg (Brf Consult). 84 Aug 104; renal failure. 84 March 263.
Blanck, Thomas JJ malignant hyperthermia. 84 June 61.
Blath, Richard A preventing renal calculi. 84 Nov 54.
Block, Robert memory dysfunction with aging. 84 Nov 136.
Botoman, V Alin evaluating weight loss. 84 Jan 258.
Braun, William E managing kidney transplant recipients. 84 Oct 135.
Breen, James L followup after anorexia (Brf Consult). 84 Sept 107.
Brest, Albert N cardioprotective effects of antihypertensive therapy. 84 June 92.

Bryan, Charles S evaluating tetanus toxoid reaction (Brf Consult). 84 July 212.
Bucholz, Robert W pediatric fractures. 84 Feb 214.
Buchsbaum, Harvey W low back pain (Puzz Case). 84 June 224.
Bye, Michael R sleep apnea in children. 84 May 77.
Bynum, TE cytoprotective prostaglandins (Brf Consult). 84 Jan 115.
Caceres, CA computerized ECG. 84 June 237.
Camara, Amanda evaluating depression (part 1). 84 Jan 37; depression management (part 2). 84 Feb 233.
Capp, M Paul current cardiac imaging techniques. 84 May 91.
Carey, William D biliary cirrhosis. 84 March 89.
Carr, Albert A hypervolemia as a cause of intractable hypertension. 84 Aug 189.
Casper, Edmund post-traumatic stress disorder in veterans. 84 May 191.
Castell, Donald O new ways to relieve heartburn, dysphagia, chest pain. 84 April 259.
Catz, Eric G updated emphysema treatment (Brf Consult). 84 Oct 179.
Cherner, Rachmel diets and the 'thyroid myth' (Brf Consult). 84 Aug 177.
Child, John S timing mitral valve replacement (Brf Consult). 84 Sept 127.
Cohen, Kenneth L pituitary function tests. 84 Dec 41.
Cohen, Stanley N impotence. 84 Aug 121.
Collins, Weldon E differentiating infectious causes of pyoderma. 84 Sept 181.
Colon, V Franklin improving gynecologic cytology techniques. 84 Aug 161.

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YEAR-END INDEX

Connor, William food and arterial plaques (Brf Consult), 84 May 106.

Coodley, Eugene L. how age-linked functional changes affect clinical decisions, 84 Oct 39.

Cooke, David H. prompt recognition and care of myocardial infarction, 84 Sept 206.

Cozen, Lewis N. selecting walking aids, 84 Jan 268.

Curtis, Peter well-woman checkup, 84 Jan 231.

Cutler, Ralph E. antihypertensive therapy, 84 March 321.

Danowski, TS eye changes and continuous insulin (Brf Consult), 84 June 111.

de Leon, Antonio C Jr heart examination based on pulsation, waves, and sounds, 84 March 111.

Deaton, John G Sjögren's syndrome (Clinical Case No. 122), 84 Oct 256.

Defronzo, Ralph A. management of type II diabetes, 84 Feb 35.

Derkx, Frederick W. antibiotics for anaerobic infections, 84 Jan 206.

Dickens, James H. managing epistaxis, 84 July 140.

Dirckx, John H. herpes genitalis (Clinical Case No. 115), 84 March 282.

Dobbins, John W. evaluating small-bowel function in malabsorption, 84 June 113.

Doris, Peter E. evaluating gas patterns on abdominal x-ray films, 84 Sept 29.

Dotz, Warren I. skin signs of internal malignancy, 84 Oct 268; ways to preserve skin hydration, 84 Aug 46.

Doucette, Margaret managing post-bypass arrhythmias, 84 Oct 115.

Douglas, R Gordon Jr flu vaccine recommendations for 1984-85, 84 Oct 33.

Driscoll, Charles E. making school physicals more productive, 84 Sept 143.

Dyck, Walter P. new drugs for peptic ulcer, 84 Feb 85.

Egan, Robert I. current recommendations for mammography, 84 April 166.

Eisenberg, Gerald M. rheumatoid arthritis and aspirin (physicians' questions), 84 June 31.

Eisenstat, Theodore E. flexible sigmoidoscopy, 84 May 39.

Ellis, Don S. retinitis pigmentosa, 84 May 51.

Ericsson, Charles D. travelers' diarrhea, 84 April 195.

Faillace, Robert T. carcinoid tumor (Puzz Case), 84 March 239.

Feldman, Jerome M. interactions of sulfonylureas with other drugs, 84 July 37.

Ferguson, Albert B. low back pain (Brf Consult), 84 Feb 167.

Fieber, Leonard acute infectious gastroenteritis, 84 July 67.

Firth, Brian G. failed prosthetic heart valve (Clinical Case No. 116), 84 April 230.

Fisher, Jack C. guide to referring problem burns, 84 April 76.

Fleming, Michael F. hazards of ionizing radiation, 84 Jan 167.

Forsyth, Roger A. criteria for diagnosis and management of hypertension, 84 Oct 306.

Friermood, Thomas G. hip and thigh injuries in sports, 84 May 157.

Fuller, Lillian M. new imaging techniques for lymphoma and Hodgkin's disease, 84 Feb 128.

Garson, Arthur Jr arrhythmias in children, 84 Nov 99.

Gershon, Samuel memory dysfunction with aging, 84 Nov 136.

Gold, Eli postsplenectomy infection, 84 Jan 301.

Goldman, Allan L. recognizing fibrositis, 84 July 55.

YEAR-END INDEX

Goldman, Lee preoperative evaluation for 'healthy' patients, 84 Jan 331.
Gray, James E pseudomembranous colitis (Puzz Case), 84 July 121.
Greenburg, Jerry L caffeineism (Clinical Case No. 119), 84 July 194.
Grekin, Roy C pictorial guide to cutaneous tumors, 84 June 69.
Hagemeister, Frederick B new imaging techniques for lymphoma and Hodgkin's disease, 84 Feb 128.
Harris, Joseph L preterm labor, 84 March 256.
Harrison, Donald C infective endocarditis, 84 April 109.
Healey, Louis A gout (Puzz Case), 84 April 159.
Heckenlively, John R retinitis pigmentosa, 84 May 51.
Herbert, William NP recurrent vaginitis, 84 Sept 46.
Hocutt, John E flexible sigmoidoscopy, 84 May 39.
Hodgkin, John E pulmonary rehabilitation, 84 Feb 73.
Hollingsworth, Dorothy Reycroft new approaches for diabetes mellitus pregnancy, 84 Aug 29.
Honig, Stephen chiropractors and a thermography scam? (Puzz Case), 84 March 81.
Hopwood, Nancy J failure to thrive, 84 June 45.

Howell, Charles surgical emergencies in neonates, 84 March 149.
Hughes, Michael F managing external otitis, 84 May 113.
Humphrey, Michael J malignant hyperthermia, 84 June 61.
Huskisson, Edward C selection criteria for NSAIDs, 84 March 41.
Illice, Martha negotiating with patients for home birth, 84 July 186.
Jacobs, John R managing epistaxis, 84 July 140.
Jacobs, Robert P management of osteoarthritis, 84 Nov 29.
Jones, Richard E diagnosing rotator cuff disease, 84 April 242.
Kaufman, Jay H eye surgery in the elderly, 84 Jan 63.
Kelly, A Paul syphilis, 84 March 173.
Kleinman, Martin S non-A, non-B hepatitis, 84 May 143.
Knochel, James P renal failure (Brf Consult), 84 March 263.
LaChance, Paul diets and the 'thyroid myth' (Brf Consult), 84 Aug 177.
Leebaw, Wayne F effects of aging on endocrine problems, 84 July 165.
Lending, Robert E low back pain (Puzz Case), 84 June 224; superior vena cava syndrome (Puzz Case), 84 Feb 321.

Lerner, Robert G duration of warfarin therapy (Brf Consult), 84 Oct 267.
Leslie, Stephen neurogenic bladder, 84 Jan 131.
Lichstein, Jacob syndrome shift, 84 Oct 299.
Liebman, Emil P investigating causes of tinnitus, 84 April 47.
Lightdale, Charles J liver cancer, 84 Feb 271.
Livingston, Samuel epilepsy, 84 Oct 237; epilepsy management (Brf Consult), 84 April 123.
Llorens, Alfred S assessing vulvovaginal cancer by office biopsy, 84 June 129.
Lueg, Mark C Graves' ophthalmopathy, 84 Feb 193; thyroid neoplasm (Clinical Case No. 117), 84 May 204.
Luff, Ronald D evaluating Class II vaginal smears, 84 Nov 177.
Maisel, Robert H oropharyngeal injuries in children, 84 Jan 186.
Make, Barry oxygen therapy for hypoxemia, 84 March 57.
Malone, John I insulin delivery (Brf Consult), 84 Feb 126.
Marier, Robert L antibiotics for anaerobic infections, 84 Jan 206.
Marquardt, Diana L procedures for allergy testing, 84 Jan 151.

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YEAR-END INDEX

- Martin, Richard J** hamartomatosis (Puzz Case), 84 Dec 97; respiratory sleep disorder (Puzz Case), 84 Sept 113; updated emphysema treatment (Brf Consult), 84 Oct 179.
- Martinsen, Kobi S** managing post-bypass arrhythmias, 84 Oct 115.
- Marzouk, Joseph B** acute infectious gastroenteritis, 84 July 67.
- Mathews, James** treatment of aspiration pneumonia, 84 Dec 25.
- Matsumori, Akira** recognizing viral myocarditis, 84 July 127.
- McHenry, Martin C** suspicious salmonella appearance (Brf Consult), 84 Jan 99.
- Mead, R Hardwin** infective endocarditis, 84 April 109.
- Metzger, W James** immunotherapy for allergic bronchial asthma, 84 Jan 240.
- Micheli, Lyle J** scoliosis and kyphosis, 84 Oct 280.
- Minaker, Kenneth L** interaction of aging and illness, 84 Feb 328.
- Mitchell, Jeffrey R** adolescent psychopathology, 84 March 267.
- Montgomery, James B** diagnosing rotator cuff disease, 84 April 242.
- Morley, John E** effects of aging on endocrine problems, 84 July 165.
- Mortimer, Joanne** cancer followup after successful treatment, 84 July 202.
- Morvant, Richard** management strategies for foot pain, 84 Aug 146.
- Murphy, Terence M** how to pick a good pain clinic, 84 July 107.
- Naide, David** duration of warfarin therapy (Brf Consult), 84 Oct 267.
- Naide, Meyer** duration of warfarin therapy (Brf Consult), 84 Oct 267.
- Nash, David T** add prazosin to prevent hyperlipidemia? (Brf Consult), 84 Dec 107.
- Nesemann, Michael E** emergency care of comatose patient, 84 Nov 192.
- Newell, Guy R** nutrition and cancer, 84 Jan 116.
- Newell, John D** current cardiac imaging techniques, 84 May 91.
- Newland, JR** leukocytosis, 84 May 221.
- Patterson, Michael M.** chiropractors and a thermography scam? (Puzz Case), 84 March 81.
- Pierce, Charles H** measuring plasma concentrations, 84 May 174.
- Pomara, Nunzio** memory dysfunction with aging, 84 Nov 136.
- Quigley, Martin M** followup after anorexia (Brf Consult), 84 Sept 107.
- Rackow, Eric** Acute heart failure, 84 Oct 227.
- Ragaz, Anna** benign and malignant skin growths, 84 May 128.
- Raisz, Lawrence G** followup after anorexia (Brf Consult), 84 Sept 107.
- Ramsby, Gale R** spinal cord tumor (Clinical Case No. 124), 84 Dec 108.
- Raskind, Robert** paralysis during sleep, 84 March 145; spinal cord tumor (Clinical Case No. 114), 84 Feb 292.
- Ratzan, Richard M** mental incompetence, assessing elderly patients, 84 Dec 88.
- Rawls, Donald E** new drugs for peptic ulcer, 84 Feb 85.
- Raynaud, Alain** current cardiac imaging techniques, 84 May 91.
- Redman, Jack C** melanoma, 84 Nov 201.
- Reiss, Eric** hypercalcemia of malignancy, 84 Sept 193.
- Renner, Gregory J** diagnosing head pain, 84 Oct 185.
- Richerson, Hal B** immunotherapy for allergic bronchial asthma, 84 Jan 240.
- Rosch, Paul J** stress and cancer, 84 Nov 73.
- Rosen, Ted** differentiating infectious causes of pyoderma, 84 Sept 181.
- Rosenberg, Ralph** spinal cord tumor (Clinical Case No. 124), 84 Dec 108.
- Roth, Ron** evaluation of cardiomegaly (part 1), 84 Jan 102; tests for cardiomegaly (part 2), 84 Feb 107.
- Rothenberg, Michael B** adolescent psychopathology, 84 March 267.
- Ruskin, Asa P** why stroke patients behave as they do, 84 Feb 177.
- Russell, Richard O Jr** right bundle branch block (Brf Consult), 84 March 295.
- Russell, Robert M** assessment of geriatric nutrition, 84 Aug 67.
- Ryan, Thomas J** digitalis controversy in perspective, 84 Nov 221.
- Sack, Kenneth E** infectious arthritis, 84 Oct 101.
- Sanders, Charles V** antibiotics for anaerobic infections, 84 Jan 206.
- Scheinman, Melvin M** ECG arrhythmia patterns (Part 1), 84 April 275; arrhythmia patterns on ECG (Part 2), 84 May 238.
- Schidlow, Daniel V** sleep apnea in children, 84 May 77.
- Schumann, Berry G** improving gynecologic cytology techniques, 84 Aug 161.
- Schwartz, Alan B** ECG arrhythmia patterns (Part 1), 84 April 275; arrhythmia patterns on ECG (Part 2), 84 May 238.
- Searles, Robert P** intractable rheumatoid arthritis (Clinical Case No. 121), 84 Sept 158.
- Selbst, Ronald A** evaluating the "confused" patient, 84 April 209.
- Shahady, Edward J** editorial opinion: communication between consultants and primary care physicians, 84 Dec 178; uncovering the real problems of 'crocks' and 'gomers,' 84 April 63.
- Shapiro, William** calcium channel blockers, 84 Dec 150.
- Sharma, Om P** brucellosis (Clinical Case No. 118), 84 June 198.
- Sholl, John G** mysterious swelling in one leg (Brf Consult), 84 Aug 104.
- Silverman, Joel J** evaluation of depression (part 1), 84 Jan 37; (part 2), 84 Feb 233.
- Simon, Harvey B** update on drug therapy for tuberculosis, 84 April 63.
- Skillman, G Thomas** osteoporosis, 84 Feb 15 3.
- Slosky, David A** managing post-bypass arrhythmias, 84 Oct 115.
- Smith, Arthur D** urinary tract dysfunction in the elderly, 84 June 181.
- Smith, Jerry A** sex counseling for teenagers, 84 July 155.
- Smith, Nathan** safe weight control for athletes, 84 Feb 247.
- Smith, Rogers J** paralysis during sleep, 84 March 145.
- Spittell, John A Jr** noninvasive office tests for occlusive arterial disease, 84 July 214.
- Strouji, Elias S** chronic headache in children, 84 Aug 78.
- Stanley, Robert B Jr** earlier diagnosis of mouth and throat carcinoma, 84 April 81.
- Stapczynski, J Stephan** oncologic emergencies, 84 Oct 207.
- Stella, Gregory J** evaluating small-bowel function in malabsorption, 84 June 113.
- Stites, Daniel P** antibody disorders, 84 Jan 284.
- Stool, Sylvan E** pediatric audiology, 84 March 131.
- Swanson, Neil A** pictorial guide to cutaneous tumors, 84 June 69.
- Terry, Luther L** smoking and health, 84 Feb 307.
- Ullrich, Bernice S** editorial opinion: An informed patient may be a better (calmer) patient, 84 May 252; editorial opinion: Why not share your tips with our readers? 84 Nov 323.
- Vincenti, Flavio G** diabetic nephropathy, 84 Jan 81.
- Wachtel, Tom J** a pain in the neck (Puzz Case), 84 Jan 253.
- Wade, Marcia** Oxygen therapy for hypoxemia, 84 March 57.
- Wagener, Jeffrey S** upper airway obstruction in children, 84 Sept 115.
- Wasserman, Stephen I** procedures for allergy testing, 84 Jan 151.
- Wassersug, Joseph D** asthma, 84 July 97.
- Weil, Max Harry** acute heart failure, 84 Oct 227.
- Weiss, Thomas E** diagnosis of painful hands by physical examination only, 84 Dec 51; low back pain (Brf Consult), 84 Feb 167.
- Wheby, Munsey S** polycythemia, 84 Dec 124.
- Whinston-Perry, Rosalind** assessment of geriatric nutrition, 84 Aug 67.
- Whitehouse, Fred W** spinal cord compression (Puzz Case), 84 Oct 199.
- Williamson, Paul S** local anesthesia for neonatal circumcision, 84 Feb 67.
- Winneford, Michael D** failed prosthetic heart valve (Clinical Case No. 116), 84 April 230.
- Wolfgang, Gary L** total hip arthroplasty, 84 March 209.
- Wolin, Preston** scoliosis and kyphosis, 84 Oct 280.
- Wolinsky, Harvey** food and arterial plaques (Brf Consult), 84 May 106.
- Ziegler, Michael G** mild hypertension, 84 Jan 320.